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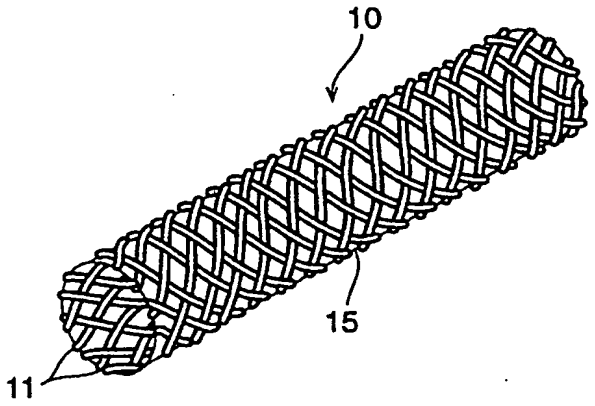
(57) Abstract

A radially self-expanding stent (10) is disclosed that is circumscribed with a matrix (15) of flexible polymeric material. This matrix (15) provides a barrier to tissue and/or tumor ingrowth. A deployment device (20) for the stent (10) includes an interior tube (30) on which the stent (10) may be placed and a hose (55) folded on itself surrounding and compressing the stent (10) on the interior tube (30).



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COVERED STENT AND STENT DELIVERY DEVICE

Background of the Invention

The present invention relates to a stent which can be used within a vessel of the body of a living animal or a living human. This invention also relates to a device for delivering the stent to the treatment site. The stent includes a flexible tubular body which has a specific diameter at an unloaded state but which can be contracted to a smaller diameter by the application of force such as by radially compressing the stent or by pulling the ends of the stent apart. This feature makes the stent particularly useful for mechanical transluminal implantation in biliary ducts, respiratory tracts, the esophagus, blood vessels or the like. The stent delivery device includes a first tube having a central lumen for accommodating a guidewire and a flexible hose folded over itself and removably surrounding the first tube. The stent is placed around the first tube and held in a radially contracted state by the flexible hose. In this manner, the stent can be delivered percutaneously and transluminally to a treatment site in a body vessel. The stent is deployed by rolling the flexible hose off of the stent to allow the stent to radially self-expand. Once the stent is deployed, the stent delivery device can be withdrawn.

Prior radially self-expanding stents have an open mesh construction. After positioning such a stent in a body vessel, tissue may grow through the spaces between the wires of the stent. In many applications, such an occurrence is not detrimental to the efficacy of the stent. Indeed in many cases such tissue ingrowth is desirable because it helps to

keep the stent in place preventing migration of the stent.

However, in certain applications, tissue ingrowth could be detrimental. For example, if the stent is to be placed in a body passage that has tumor growth therein to maintain the patency of the body passage, tumor ingrowth through the stent would limit the effectiveness of the stent. Indeed tumor ingrowth could completely block the body vessel. In addition, such tumor ingrowth would permanently "lock" the stent in place. In certain applications where the ability to remove the stent is a consideration, that is undesirable.

Prior delivery devices for radially self-expanding stents generally perform in accordance with their intended purposes. Typical prior delivery devices have a moveable tubular member that constrains the stent in a contracted state on an inner catheter. The tubular member is removed from contact with the stent to allow the stent to be deployed. In certain devices, the tubular member is folded over itself to form a double-walled section. However, such prior delivery devices may not be totally effective in delivering a stent to a treatment site. For instance, friction between the walls of the double-walled section of the moveable tubular member as the walls move past each other can make removal of the tubular member from the stent difficult. One means of minimizing this problem is by the application of pressure between the walls of the tubular member to move the walls of the tubular member away from contact with each other. However, this makes the delivery device difficult to operate. The operator of the delivery device must continuously

monitor the pressure to ensure that the pressure is maintained in a certain range. If the pressure is too low, friction forces will not be overcome. If the pressure it too high, the delivery device could rupture.

Therefore, it would be desirable to provide a stent that will maintain the patency of a body vessel and reduce the tissue ingrowth through the stent.

It would also be desirable to provide a stent that is removably placeable within a body vessel.

It would be further desirable to provide a stent delivery device that can deploy a stent at a treatment site with little difficulty.

Summary of the Invention

These and other objects are achieved by the covered stent of the present invention. The covered stent comprises a flexible tubular body, the diameter of which can be changed by radial compression of the stent or by axial movement of the ends of the body relative to each other. The covered stent takes on a specified diameter when it is left in an unloaded condition free of external forces. The body is composed of several individual, rigid but flexible thread elements each of which extends in a helix configuration with the center line of the body as a common axis. A number of such thread elements have the same direction of winding but are displaced axially relative to each other. The remaining thread elements have the opposite direction of winding and are also axially displaced to each other. Thus, each thread element crosses a number of other thread elements in an over and under braided configuration.

The stent is also covered with a continuous and flexible polymeric matrix that is preferably silicone

rubber. This covering limits tissue ingrowth through the stent when the stent is implanted in a body vessel. The film is preferably applied to the stent by dip coating the stent in a bath of silicone rubber and an organic solvent. The thickness of the film can be controlled by the ratio of the silicone rubber and organic solvent in the bath and by the number of dip coatings to which the stent is subjected.

The stent delivery device includes an elongate and flexible length of inner tubing with a central lumen for accommodating a guidewire. The stent is placed on this tubing in a radially contracted state for transport to the treatment site. A flexible hose surrounds the tubing and is folded over itself to form a double-walled section. This double-walled section surrounds and confines the stent in a radially contracted state on the tubing. To facilitate the movement of the flexible hose away from the stent, at least that portion of the hose that contacts itself in the double-walled section is lubricous. This lubricous characteristic can be achieved by placing a lubricous coating on the surface of the hose that contacts itself in the double-walled section of the hose, by injecting a lubricous liquid into the space between the walls of the double-walled section or by forming the flexible hose from a naturally lubricous material. This makes the stent delivery device of the present invention easy to use and makes simple the deployment of a stent therefrom.

When it is desired to deploy the stent at a treatment site, the flexible hose is rolled back proximally to first expose the distal end of the stent. This allows the operator of the stent

delivery device first to align properly the distal portion of the stent in the body vessel. When proper alignment is obtained, the operator can continue to roll the flexible hose proximally to completely uncover the stent and allow it to radially self-expand into engagement with the vessel wall.

Brief Description of the Drawings

The above and other objects and advantages of this invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout and in which:

FIG. 1 is a perspective view of the covered stent of this invention clearly showing the braided configuration of the thread elements;

FIG. 2 is a perspective view of the covered stent of this invention in a radially contracted state clearly showing the braided configuration of the thread elements;

FIG. 3 is a cross-sectional view taken along line 3-3 in FIG. 9.

FIG. 4 is a detailed view in perspective of a portion of the stent of this invention without the covering to show the braided configuration of the thread elements;

FIG. 5 is a detailed sectional view of a portion of the stent of this invention without the covering to show the braided configuration of the thread elements;

FIG. 6 is a diagrammatic sectional view of a portion of the covered stent of this invention showing the flexible polymeric matrix located along the exterior of the stent;

FIG. 7 is a view similar to the view of FIG. 6 with the flexible polymeric matrix located along the interior of the stent;

FIG. 8 is a side view of the stent delivery device of this invention with a covered stent loaded therein;

FIG. 9 is an enlarged side view of the area encircled at 9 in FIG. 8;

FIG. 10 is an enlarged side view of the area encircled at 10 in FIG. 8; and

FIGS. 11-14 are side views of a distal portion of the stent delivery device and the covered stent of the present invention in various stages of a stent deployment operation in a body vessel.

Detailed Description of the Invention

In FIG. 1 there is shown an example of the covered stent 10 of the present invention in an unloaded condition. Covered stent 10 is in the form of a cylindrical tubular body. Stent 10 is formed by a number of individual thread elements 11. Some of these elements extend in helix configuration in one direction axially displaced in relation to each other having the center longitudinal axis of stent 10 as a common axis. The other elements extend in helix configuration in the opposite direction and are also axially displaced in relation to each other having the center longitudinal axis as a common axis. Thus thread elements 11 extend in two directions and cross each other in a braided over and under configuration.

Thread elements 11 of stent 10 are preferably arranged symmetrically so that the same number of thread elements are used in each direction of a winding. The number of thread elements needed is a function of the diameter of stent 10 in an unloaded

condition. For a stent having a diameter of 10 millimeters preferably 24 thread elements are used. Thread elements 11 are helically wound about a cylindrical mandrel. One set of thread elements is wound in one direction while the other set of thread elements is wound in the opposite direction.

Thread elements 11 should be maintained in tension. Insufficient tensile force may allow the individual thread elements to depart from their configuration causing the braided structure of stent 10 to unravel. When thread elements 11 are properly tensioned, a slight impression is formed in the overlying thread element at each intersection. See FIGS. 4 and 5. Each thread element is thus deformed such that it is bent over other thread elements and partly circumscribes these other thread elements. Generally, only the parts of the respective thread elements lying on top of the crossing thread elements as seen in the radial direction have been subject to bending. These impressions, or saddles, tend to lock the thread elements relative to one another at the intersections. This maintains the stent configuration without the need for welding or other bonding of thread elements 11 at their intersections. In addition, this allows a suitable length of the tubular braid to be cut in order to make a stent of the desired length. The cut length of the tubular braid essentially maintains its cylindrical shape at the end sections.

In order to further improve the radial stability of stent 10, the axially directed angle between crossing thread elements should be at least 60°, preferably greater than about 90° and even more preferably greater than about 100° when stent 10 is

in an unloaded condition. The greater the angle, the higher the stability of stent 10 under external pressure.

Thread elements 11 forming stent 10 can be made from a biocompatible and flexible yet rigid material such as various polymers, e.g. Kevlar, and metal such as stainless steel. Other materials include alloys substantially based on cobalt, chromium, nickel and molybdenum, the alloying residue being iron. In addition, thread elements 11 can be formed from a core and a tubular case surrounding the core. This configuration can enhance the radiopacity of stent 10. For example, the core can be constructed of tantalum for radiopacity while the case can be constructed of a cobalt-based alloy such as an alloy available under the brand name "Elgiloy", "Phynox" and "MP35N". Such a clad composite thread element for use in making a stent is described in commonly assigned, co-pending patent application Serial No. 08/006,216 filed on January 19, 1993, which is hereby incorporated by reference.

The diameter of stent 10 can be changed by radially compressing stent 10 or by axially displacing the ends of stent 10 relative to each other. In FIG. 2 there is illustrated how stent 10 according to FIG. 1 has been given reduced diameter by moving the ends away from each other in the direction of the arrows. Since stent 10 must engage against the wall of the body vessel in which stent 10 is to be placed with certain pressure in order to remain fixed, the diameter of stent 10 in the radially contracted state must be smaller than the diameter of stent 10 at free expansion.

Stent 10 is covered by a matrix 15 of a flexible, polymeric material such as silicone rubber, polyurethane or Teflon. Other flexible and biocompatible polymers could also be used. Preferably silicone rubber is used. Matrix 15 can take the form of a film or a braided or woven covering.

Matrix 15 is preferably applied to stent 10 by dip coating. Liquid silicone rubber is mixed with an organic solvent, preferably xylene, to make the silicone rubber flowable. For a stent having a diameter of 10 mm, 24 thread elements and a braid angle of 110° and where the stent is supported in the silicone rubber and xylene bath only at the ends, a ratio of 27% silicone rubber to xylene is preferably used. Using this arrangement only one dip coating is needed to completely cover stent 10. For a stent having a diameter of 20 mm, 36 thread elements and a braid angle of 110° and where the stent is supported in the silicone rubber and xylene bath by an internal mandrel, a ratio of 18% silicone rubber to xylene is preferably used. Using this arrangement 3 to 5 dip coatings is needed to completely cover stent 10.

Additional coats could be applied to stent 10 beyond what is described above. However, if too many coats are used, the flexibility of the resulting stent will be compromised making it difficult to load the resulting stent on a delivery device or to deploy the resulting stent at a treatment site. It has been found that a coating about .004 inches thick is preferable. Alternatively, if a matrix 15 with more flexibility is desired, matrix 15 can take the form of a braided or woven covering.

Stent 10 can be dip coated by supporting the ends of stent 10, by using an external mandrel or by using an internal mandrel to support stent 10 when it is dipped in the bath of silicone rubber and xylene. When stent 10 is dip coated by supporting the ends of stent 10, the silicone rubber surrounds thread elements 11 so that the silicone rubber only extends in the interstices between thread elements 11 and there is little excess silicone rubber on the outside or inside of stent 10. See FIG. 3 and FIG. 14. When stent 10 is supported by an external mandrel the silicone rubber coating tends to extend toward the outside of thread elements 11 forming stent 10. See FIG. 6. When stent 10 is supported by an internal mandrel the silicone rubber tends to extend toward the inside of thread elements 11 forming stent 10. See FIG. 7. Preferably, stent 10 should be supported at the ends or by an external mandrel during the dip coating process. The matrix resulting from this process tends to be stronger and more tear resistant so that it is better able to prevent tissue ingrowth through the interstices between thread elements 11 forming stent 10.

Although the dip coating process described above is the preferred process for covering the stent of this invention, matrix 15 can also be applied by other methods such as by injection molding or spray coating stent 10 with the polymeric material.

Stent 10 is placed on a stent delivery device 20 in a radially contracted state for delivery to the treatment site in a body vessel. Stent 10 is carried by the distal portion of delivery device 20. The

proximal portion of delivery device 20 generally remains outside of the body for manipulation by the operator.

Delivery device 20 comprises an elongated, inner tube 30, preferably having an axially extending lumen 35 therethrough. A distal portion of inner tube 30 is flexible and can be made from nylon or any other suitably flexible biocompatible polymeric material. At its distal end, inner tube 30 is provided with a head 31, through which lumen 35 continues. Head 31 serves to facilitate the insertion of delivery device 20 through a narrow opening in a body vessel. The proximal portion of inner tube 30 is preferably formed from stainless steel or some other suitably rigid metal alloy. The proximal end of the distal portion of inner tube 30 is bonded to the distal end of the proximal portion of inner tube 30 in any conventional manner such as by using a standard adhesive.

A proximal tube 50 surrounds the proximal portion of inner tube 30 in coaxial fashion. Preferably proximal tube 50 is formed from polyurethane. The proximal end of proximal tube 50 is connected to a valve body 40 having a side port 41. An extension tube 45 extends from side port 41 to an opening 42. This arrangement allows fluid to be injected through extension tube 45 and between proximal tube 50 and inner tube 30.

A moveable hose 55 surrounds the distal portion of inner tube 30. Hose 55 is rolled over itself to form a double-walled section. The proximal end of the inner wall 56 of the double-walled section is connected directly to inner tube 30. The proximal end of the outer wall 57 of the double-walled section

is connected to the outer surface of the distal portion of proximal tube 50. These connections can be achieved by any conventional means such as by a standard adhesive. This arrangement allows hose 55 to be rolled off stent 10 placed on the distal portion of inner tube 30. By moving valve body 40 in the proximal direction, outer wall 57 of hose 55 slides proximally over inner wall 56. This causes inner wall 56 to "roll back" off of stent 10. To facilitate movement of hose 55 off of stent 10, at least that portion of inner wall 56 that contacts outer wall 57 in the area where hose 55 is folded over to form the double-walled section should be lubricous.

The lubricous characteristic can be achieved by adding a lubricous substance to this surface of hose 55, injecting a lubricous liquid between inner wall 56 and outer wall 57 or forming hose 55 from a naturally slippery material such as Teflon.

In the preferred embodiment, at least the surfaces of inner wall 56 and outer wall 57 that face each other in the double-walled section are coated with a lubricous hydrophilic coating. Preferably a hydrophilic coating manufactured and sold by The Hydromer Company under the designation 2018-M is used. Other materials include polyethylene oxide and hyaluronic acid. When wet the hydrophilic coating becomes lubricous and thus reduces friction between inner wall 56 and outer wall 57 of the double-walled section of hose 55 as outer wall 57 moves past inner wall 56. This facilitates the removal of the double-walled section of hose 55 from stent 10.

Preferably, hydrophilic material is added to hose 55 during the assembly of delivery device 20.

In order for the hydrophilic material to adequately bond to hose 55, the material used to manufacture hose 55 must be matched to the hydrophilic material used. It has been found that polyurethane works well as the material to form hose 55. In particular, a blend of 65D and 75D polyurethane provides sufficient flexibility to allow hose 55 to roll over itself yet still be soft enough and compatible with the hydrophilic material so it can be properly coated. Preferably the blend is composed of 50% 65D polyurethane and 50% 75D polyurethane.

During the assembly of delivery device 20, one side of hose 55 is coated with the hydrophilic material after hose 55 (outer wall 57) has been connected to proximal tube 50. Isopropyl alcohol is first applied to one side of hose 55 to clean the surface and remove the waxy film resulting from the plasticizers in the polyurethane. Next that same side of hose 55 is coated with the hydrophilic material. The surface of hose 55 should be flushed with alcohol for about 30 seconds. Similarly, that surface of hose 55 should be flushed with the hydrophilic coating for about 30 seconds. It has been found that this technique deposits sufficient hydrophilic material on inner wall 56 and outer wall 57 to allow hose 55 to be rolled back with minimal friction when the hydrophilic material is wet.

Once delivery device 20 has been assembled and is ready for use, the hydrophilic coating is wetted with physiological saline solution by injecting the solution through extension tube 45, past proximal tube 50 and into the space between inner wall 56 and outer wall 57 of the double-walled section of hose 55. Excess fluid exits from the hole 59 formed

toward the distal end of the double-walled section of hose 55. In this same manner, a lubricous fluid such as polyethylene glycol can be injected into the space between inner wall 56 and outer wall 57 of the double-walled section to provide the lubricous characteristic of hose 55 in place of adding a lubricous hydrophilic material to hose 55 as described above.

To deliver stent 10 to a treatment site in a body vessel, stent 10 is placed in a radially compressed state in a surrounding relationship to the outer distal end of inner tube 30. Stent 10 is constrained on inner tube 30 by the double-walled section of hose 55. It is important that stent 10 not be confined too tightly on inner tube 30. Hose 55 should apply just enough force to stent 10 to hold stent 10 in place. The double-walled section of hose 55 can be removed from surrounding relation to stent 10 by pulling valve body 40 and proximal tube 50 in a proximal direction. The double-walled section "rolls" off of stent 10. No sliding movement takes place between stent 10 and inner wall 56 which contacts stent 10. Along with the movement of the double-walled section in a proximal direction, the distal end of stent 10 will be exposed in a radial direction to engagement against the wall of the body vessel. See FIG. 13. As the double-walled section of hose 55 continues moving proximally, more of stent 10 expands in a radial direction until the entire length of stent 10 is exposed and engages the wall of a body vessel. See FIG. 14.

Lumen 35 is used to allow stent delivery device 20 to follow a guidewire (not shown) previously inserted percutaneously into the body vessel. Lumen

35 of inner tube 30 can also be used to introduce a contrast fluid to the area around the distal end of delivery device 20 so that the position of delivery device 20 may be easily detected for example by using X-ray technique.

Thus it is seen that a covered stent is provided that maintains the patency of a body vessel and reduces tissue ingrowth through the stent. In addition, a stent delivery device is provided that minimizes friction between moving parts and that can deploy a covered stent at a treatment site with little difficulty. One skilled in the art will appreciate that the described embodiments are presented for purposes of illustration and not of limitation and that the present invention is only limited by the claims which follow.

CLAIMS

What is claimed is:

1. A stent (10), comprising:

a first plurality of thread elements (11) each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding and which are axially displaced relative to each other;

a second plurality of thread elements (11) each of which extends in a helix configuration along the center line of the stent and having a second common direction of winding and being axially displaced relative to each other so as to cross the first plurality of thread elements (11) and form a plurality of interstices between each of the thread elements (11);

the first plurality of thread elements (11) and the second plurality of thread elements (11) together define a stent inner surface and a stent outer surface; and

a matrix of polymeric material (15) covering the stent so as to occlude the interstices between each of the thread elements (11) of the stent.

2. The stent (10) of claim 1 wherein the polymeric material is silicone rubber.

3. The stent (10) of claim 1 wherein the polymeric material is polyurethane.

4. The stent (10) of claim 1 wherein the polymeric material is Teflon.

5. The stent (10) of claim 1 wherein the matrix (15) occluding the interstices is about .004 inches thick.

6. The stent (10) of claim 2 wherein the matrix (15) occluding the interstices is about .004 inches thick.

7. The stent (10) of claim 3 wherein the matrix (15) occluding the interstices is about .004 inches thick.

8. The stent (10) of claim 4 wherein the matrix (15) occluding the interstices is about 0.004 inches thick.

9. The stent (10) of any of claims 1-8 wherein the matrix (15) of polymeric material extends toward the outer surface of the stent.

10. The stent (10) of any of claims 1-8 wherein the matrix (15) of polymeric material extends toward the inner surface of the stent.

11. A device (20) for implanting a stent in a body passage, comprising:

an elongate inner tube (30) having a distal portion and a proximal portion wherein at least the distal portion is flexible;

a proximal tube (50) coaxially disposed around the proximal portion of the elongate inner tube (30);

a hose (55) surrounding a portion of the distal portion of the elongate inner tube (30), the hose (55) being folded on itself to form a double-walled section having an inner wall and an outer wall and wherein the inner wall is connected to the elongate inner tube (30) and the outer wall is connected to the proximal tube (50); and

a lubricous coating on a surface of at least one of the inner wall or the outer wall of the double-walled section of the hose (55).

12. The device (20) of claim 11 wherein the lubricous coating is hydrophilic.

13. A device (20) for deploying a radially, self-expanding stent, comprising:

an elongate inner tube (30) having a distal portion and a proximal portion wherein at least the distal portion is flexible;

a radially expandable stent (10) covered by a matrix (15) of polymeric material surrounding a portion of the elongate inner tube (30);

a proximal tube (50) coaxially disposed around the proximal portion of the elongate inner tube (30);

a hose (55) surrounding a portion of the distal portion of the elongate inner tube (30) and the stent (10) so as to maintain the stent (10) in a radially contracted state on the elongate inner tube (30), the hose (55) being folded on itself to form a double-walled section having an inner wall and an outer wall and wherein the inner wall is connected to the elongate inner tube (30) and the outer wall is connected to the proximal tube (50); and

a lubricous coating on a surface of at least one of the inner wall or the outer wall of the double-walled section of the hose (55).

14. The device (20) of claim 13 wherein the radially, self-expanding stent (10) comprises:

a first plurality of thread elements (11) each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding and which are axially displaced relative to each other;

a second plurality of thread elements (11) each of which extends in a helix configuration along

the center line of the stent and having a second common direction of winding and being axially displaced relative to each other so as to cross the first plurality of thread elements (11) and form a plurality of interstices between each of the thread elements (11);

the first plurality of thread elements (11) and the second plurality of thread elements (11) together define a stent inner surface and a stent outer surface; and

wherein the matrix (15) of polymeric material covers the stent so as to occlude the interstices between each of the thread elements (11) of the stent.

15. The device (20) of claim 13 wherein the polymeric material is silicone rubber.

16. The device (20) of claim 14 wherein the polymeric material is silicone rubber.

17. The device (20) of claim 13 wherein the polymeric material is polyurethane.

18. The device (20) of claim 14 wherein the polymeric material is polyurethane.

19. The device (20) of claim 13 wherein the lubricous coating is hydrophilic.

20. The device (20) of claim 13 wherein the lubricous coating is polyethylene oxide.

21. The device (20) of claim 13 wherein the lubricous coating is hyaluronic acid.

22. The device (20) of claim 14 wherein the lubricous coating is hydrophilic.

23. The device (20) of claim 14 wherein the lubricous coating is polyethylene oxide.

24. The device (20) of claim 14 wherein the lubricous coating is hyaluronic acid.

25. The device (20) of any of claims 13-24 wherein the matrix (15) of polymeric material is about .004 inches thick.

26. A device (20) for implanting a stent (10) in a body passage, comprising:

an elongate inner tube (30) having a distal portion and a proximal portion wherein at least the distal portion is flexible;

a proximal tube (50) coaxially disposed around the proximal portion of the elongate inner tube (30); and

a hose (55) formed from lubricous material surrounding a portion of the distal portion of the elongate inner tube (30), the hose (55) being folded on itself to form a double-walled section having an inner wall and an outer wall and wherein the inner wall is connected to the elongate inner tube (30) and the outer wall is connected to the proximal tube (50).

27. The device (20) of claim 26 further comprising a radially expandable stent (10) covered by a matrix (15) of polymeric material surrounding a portion of the elongate inner tube (30).

28. The device (20) of claim 27 wherein the radially, self-expanding stent (10) comprises:

a first plurality of thread elements (11) each of which extends in a helix configuration along a center line of the stent and having a first common direction of winding and which are axially displaced relative to each other;

a second plurality of thread elements (11) each of which extends in a helix configuration along the center line of the stent and having a second common direction of winding and being axially

displaced relative to each other so as to cross the first plurality of thread elements (11) and form a plurality of interstices between each of the thread elements (11);

the first plurality of thread elements (11) and the second plurality of thread elements (11) together define a stent inner surface and a stent outer surface; and

wherein the matrix (15) of polymeric material covers the stent so as to occlude the interstices between each of the thread elements of the stent.

29. The device (20) of claim 26 wherein the lubricous material is Teflon.

30. The device (20) of claim 27 wherein the lubricous material is Teflon.

31. The device (20) of claim 28 wherein the lubricous material is Teflon.

32. The device (20) of any of claims 27, 28, 30 or 31 wherein the matrix (15) of polymeric material is silicone rubber.

33. The device (20) of any of claims 27, 28, 30 or 31 wherein the matrix (15) of polymeric material is polyurethane.

34. A method of deploying a radially, self-expanding stent (10) covered by a matrix (15) of polymeric material from a device (20) having an elongate inner tube (30) having a distal portion and a proximal portion wherein the stent (10) surrounds the distal portion for delivery to a treatment site and at least the distal portion is flexible, a proximal tube (50) coaxially disposed around the proximal portion of the elongate inner tube (30), a hose (55) surrounding a portion of the distal portion

of the elongate inner tube (30) on which the stent (10) is located to maintain the stent (10) in a radially contracted state, the hose (55) being folded on itself to form a double-walled section defined by an inner wall and an outer wall and wherein the inner wall is connected to the elongate inner tube (30) and the outer wall is connected to the proximal tube (50), comprising:

injecting a lubricous fluid between the inner wall and the outer wall of the double-walled section of the hose (55);

inserting the device (20) into a body vessel and advancing the device (20) to a treatment site in the body vessel; and

moving the outer wall of the double-walled section of the hose (55) in a proximal direction away from contact with the stent (20) to allow the stent (20) to radially expand into engagement with the body vessel.

35. The method of claim 32 wherein the lubricous fluid is polyethylene glycol.

FIG. 1

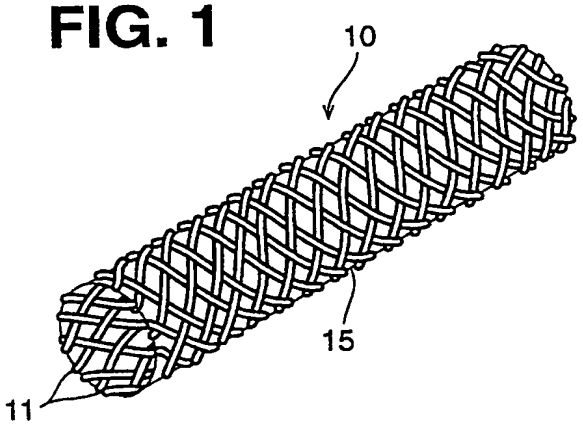


FIG. 2

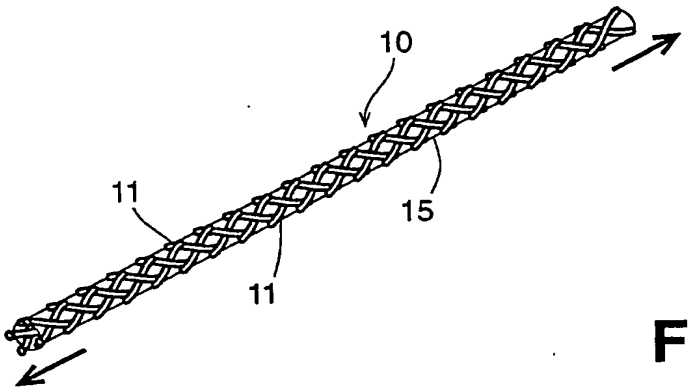


FIG. 3

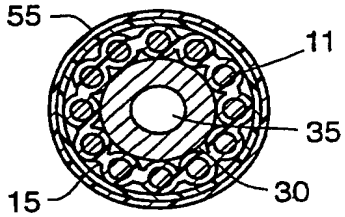


FIG. 4

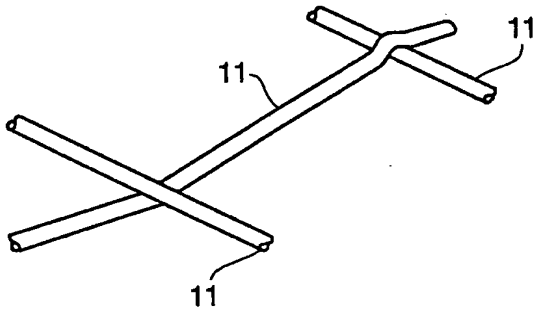


FIG. 5

FIG. 6a

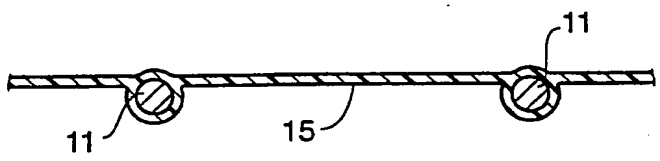


FIG. 6b

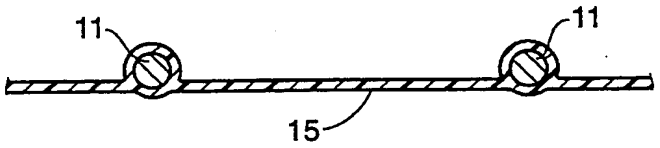


FIG. 7a

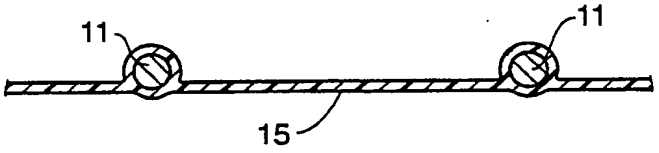


FIG. 7b

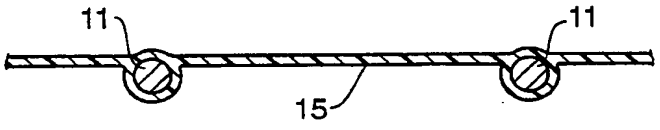


FIG. 8

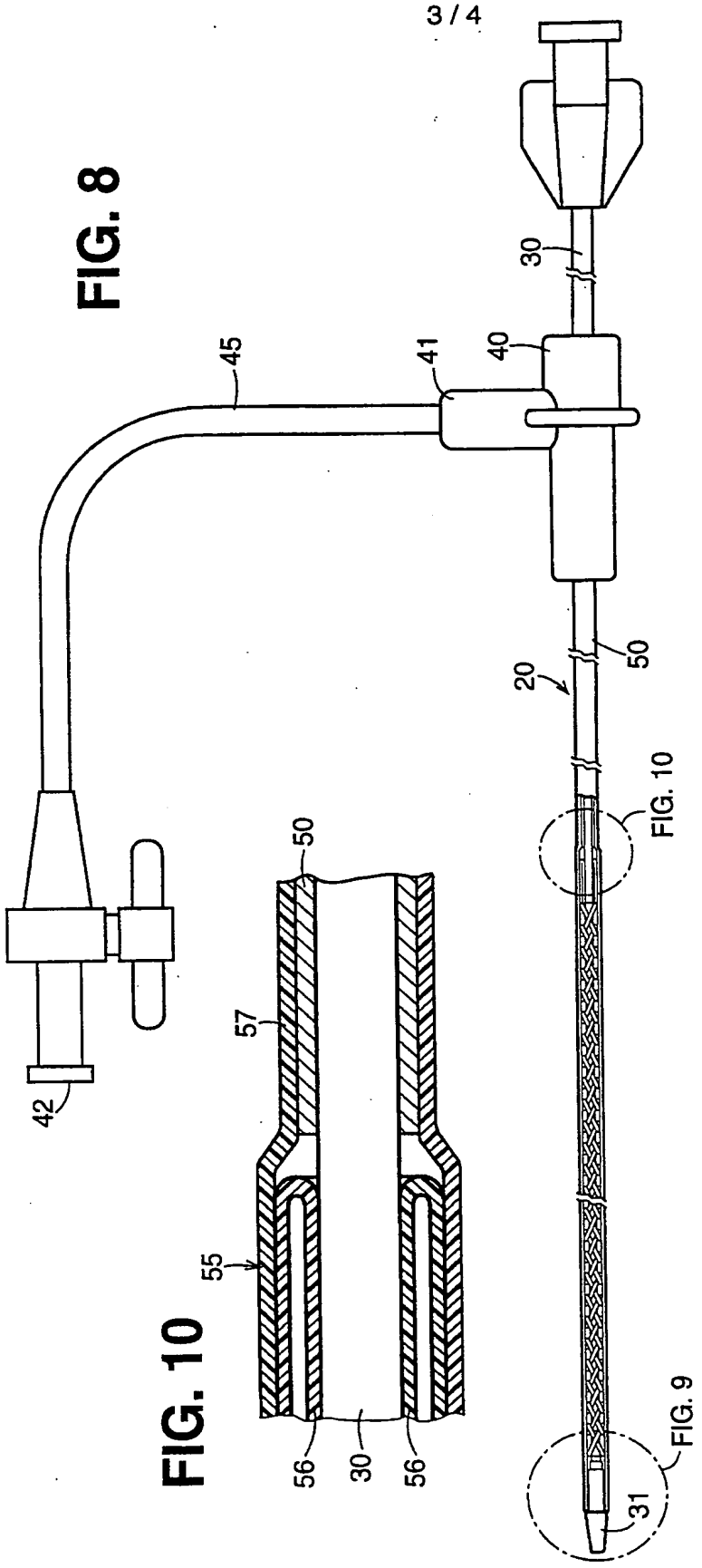
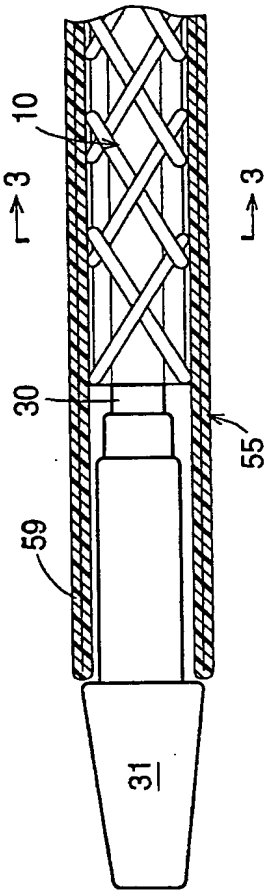


FIG. 10

FIG. 9



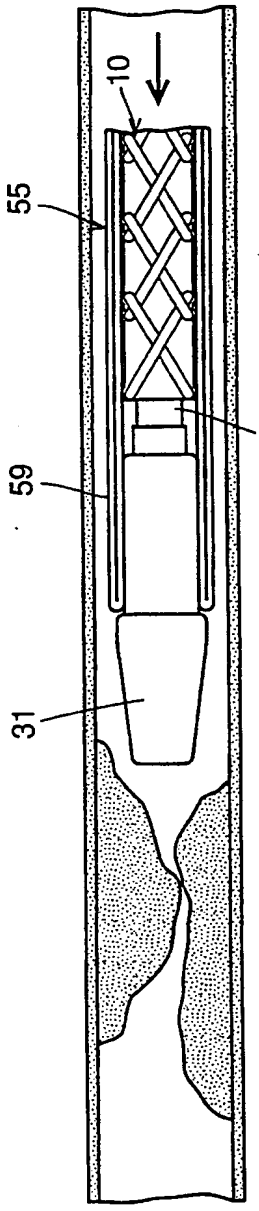


FIG. 11

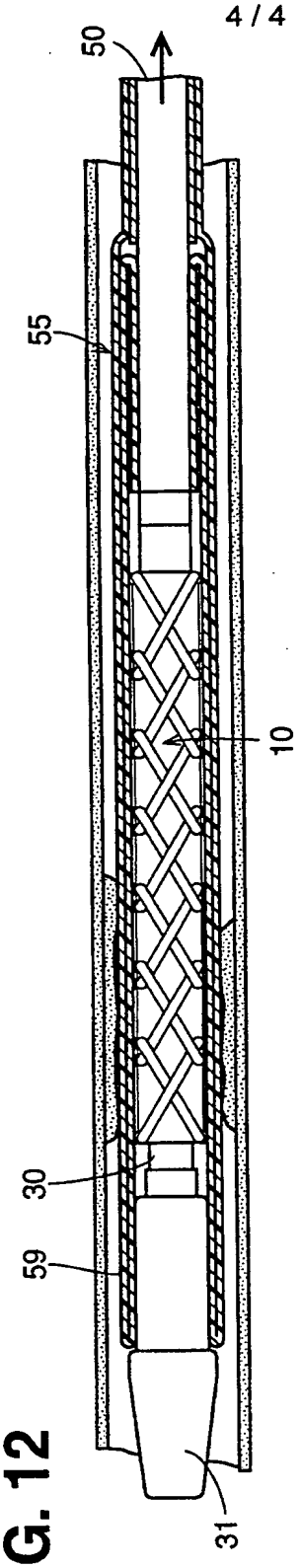


FIG. 12

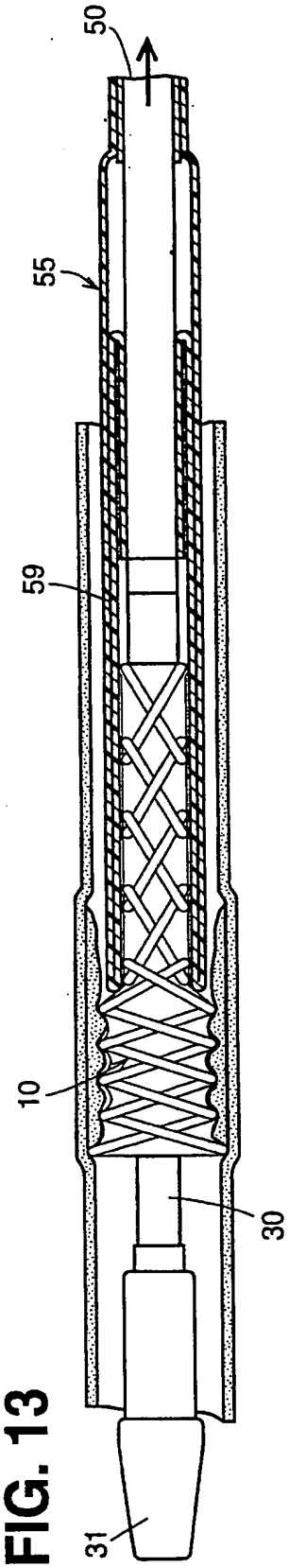


FIG. 13

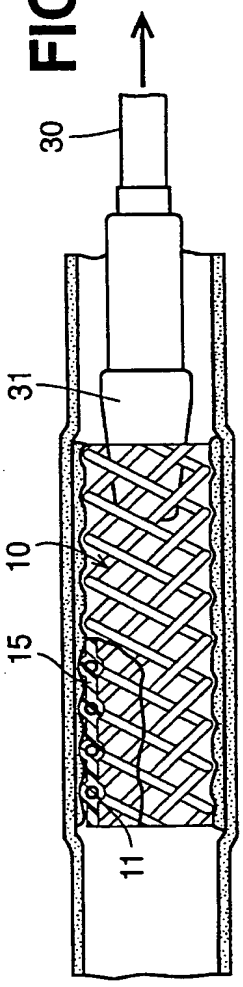


FIG. 14

INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 94/00604

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61F2/06 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP,A,0 481 365 (ANGIOMED) 22 April 1992 see claims 9,25; figure 3	1,2 3-10, 13-20, 22,23, 25,27, 28,30-33

Y	DE,A,40 22 956 (S. FREUDENBERG) 6 February 1992 see column 4, line 18 - line 51 see column 6, line 58 - column 7, line 1; figure 3	3,4,17, 18,33

Y	EP,A,0 435 518 (MED INSTITUTE) 3 July 1991 see column 3, line 50 - column 4, line 33; figure 2	5-8,25

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 April 1994	09. 05. 94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Wolf, C

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INTERNATIONAL SEARCH REPORT

Int. ional Application No
PCT/US 94/00604

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE,A,39 18 736 (C. VALLBRACHT) 13 December 1990	9,10
A	see claims 1-5; figures	4
X	WO,A,88 01924 (RAYCHEM CORPORATION) 24 March 1988	11,12, 19,26,29
Y	see abstract see page 11, line 1 - page 12, line 17 see page 17, line 1 - page 18, line 22 see page 22, line 17 - line 20 see page 35, line 21 - line 24	13-20, 22,23, 25,27, 28,30-33
X	GB,A,1 205 743 (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 16 September 1970 see page 1, line 11 - line 30; figures 1,2,4	1
X	WO,A,92 21399 (RTC INC.) 10 December 1992 see page 7, line 13 - page 9, line 11	11,12, 26,29
X	DE,A,33 29 176 (STERIMED) 22 November 1984 see abstract see column 3, line 11 - line 15; figures	11,12
A	GB,A,2 195 257 (MEDINVENT) 7 April 1988 see abstract; figures	11,13,26

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/00604

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 34-35
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatment of the human body by surgery.
Please see Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 94/00604

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0481365	22-04-92	DE-U-	9014230	21-11-91
		EP-A-	0587197	16-03-94
		JP-A-	4256759	11-09-92
DE-A-4022956	06-02-92	NONE		
EP-A-0435518	03-07-91	JP-A-	4122266	22-04-92
DE-A-3918736	13-12-90	NONE		
WO-A-8801924	24-03-88	EP-A-	0282585	21-09-88
		JP-T-	1500810	23-03-89
GB-A-1205743	16-09-70	NONE		
WO-A-9221399	10-12-92	CA-A-	2110802	10-12-92
DE-A-3329176	22-11-84	WO-A-	8500097	17-01-85
		EP-A,B	0147459	10-07-85
		US-A-	4615331	07-10-86
GB-A-2195257	07-04-88	NONE		